

IN THE CLAIMS

Please amend claims 1-35 as follows:

1. (Amended) A solid unit dosage form comprising citalopram which is prepared by direct compression of a mixture of citalopram base or a pharmaceutically acceptable salt and pharmaceutically acceptable excipients, or by filling of said mixture in a hard gelatine capsule.

2. (Amended) The solid unit dosage form according to claim 1 which is a tablet prepared by direct compression of a mixture of citalopram base or a pharmaceutically acceptable salt thereof and pharmaceutically acceptable excipients.

3. (Amended) The solid unit dosage form according to claim 1 which is prepared by filling a mixture of citalopram base or a pharmaceutically acceptable salt thereof and pharmaceutically acceptable excipients in a hard gelatine capsule.

4. (Amended) The solid unit dosage form according to claim 1 which does not contain a binder.

5. (Amended) The solid unit dosage form according to claim 1 which contains 2-60% w/w active ingredient calculated as citalopram base.

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6. (Amended) The solid unit dosage form according to claim 1 which contains a filler selected from lactose, sugars, calcium phosphates, starch, modified starches, microcrystalline cellulose, calcium sulfate and calcium carbonate.

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7. (Amended) The solid unit dosage form according to claim 6, wherein the filler is a microcrystalline cellulose.

8. (Amended) The solid unit dosage form according to claim 1 which contains a lubricant selected from metallic stearates, stearic acid, wax, hydrogenated vegetable oil, talc and colloidal silica.

9. (Amended) The solid unit dosage form according to claim 8, wherein the lubricant is magnesium stearate or calcium stearate.

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10. (Amended) The solid unit dosage form according to claim 1 which is substantially free of lactose.

11. (Amended) The solid unit dosage form according to claim 1 wherein the active ingredient is citalopram base.

12. (Amended) The solid unit dosage form according to claim 1 wherein the active ingredient is citalopram hydrobromide or citalopram hydrochloride.

13. (Amended) The solid unit dosage form according to claim 12, wherein the active ingredient is citalopram hydrobromide.

14. (Amended) The solid unit dosage form according to claim 12, wherein the active ingredient is in the form of crystals with a median particle size below 20 μ m.

15. (Amended) The solid unit dosage form according to claim 12, wherein the active ingredient is in the form of crystals with a median particle size of at least 40 μ m.

11 16. (Amended) Crystals of a pharmaceutically acceptable salt of citalopram wherein the median particle size of the crystals is at least 40 μ m.

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Cont. 12 17. (Amended) Crystals according to claim 16, wherein the crystals are of citalopram hydrobromide or citalopram hydrochloride.

13 18. (Amended) Crystals according to claim 17, wherein the crystals are of citalopram hydrobromide.

14-19. (Amended) Crystals according to claim 16, wherein the median particle size of the crystals is in the range of 40 - 200 μ m.

20. (Amended) Method for manufacture of crystals of a pharmaceutically acceptable salt of citalopram having a median particle size of at least 40 μ m wherein a solution of a pharmaceutically acceptable salt of citalopram in a suitable solvent system at a first temperature is first cooled down to a second temperature then seeded by addition of crystals of said citalopram salt followed by a holding time at said second temperature and a controlled cooling down to a third temperature whereupon said crystals are isolated by conventional solid/liquid separation techniques.

16-21. (Amended) The method according to claim 20, wherein the median particle size of the crystals is in the range of 40 - 200 μ m.

22. (Amended) The method according to claim 20, wherein the dissolved substance is citalopram hydrobromide or citalopram hydrochloride.

23. (Amended) The method according to claim 22, wherein the dissolved substance is citalopram hydrobromide.

19-24. (Amended) The method according to claim 20, wherein the solvent system comprises one or more alcohols and optionally water.

20-25. (Amended) The method according to claim 24, wherein the solvent system is a mixture of methanol and water.

21-26. (Amended) The method according to claim 25 wherein the methanol:water weight ratio is in the range of 5:1 to 50:1.

22-27. (Amended) The method according to claim 20 wherein the solvent:solute weight ratio is in the range of 0.5:1 to 5:1.

23-28. (Amended) The method according to claim 20 wherein said first temperature is in the range between 50°C and the refluxing temperature of the solvent system.

24-29. (Amended) The method according to claim 20 wherein said second temperature is in the range of 20-40°C.

30. (Amended) The method according to claim 20 wherein said holding time is in the range of 30 minutes to 7 days.

26¹⁵ (Amended) The method according to claim 20 wherein said third temperature is in the range of 0-20°C.

27¹⁵ (Amended) The method according to claim 20 wherein said controlled cooling down is a gradual cooling down over a time span in the range of 5 minutes to 6 hours.

33. (Amended) The method according to claim 20 wherein said isolation of the crystals of a pharmaceutically acceptable salt of citalopram from the mother liquor is performed by filtration.

34. (Amended) A solid unit dosage form prepared by directly compressing a mixture of citalopram base or a pharmaceutically acceptable citalopram salt and pharmaceutically acceptable excipient.

35. (Amended) A solid unit dosage form comprising citalopram prepared by filling in a hard gelatin capsule with a mixture comprising citalopram base and a pharmaceutically acceptable excipient.

Please add new claims 36-61 as follows:

--36. (New) The solid unit dosage form of claim 1, which contains 10-40% w/w active ingredient calculated as citalopram base.

37. (New) The solid unit dosage form of claim 1, which contains 15-25% w/w active ingredient calculated as citalopram base.

38. (New) The solid unit dosage form of claim 6, wherein said filler is a sugar selected from the group consisting of sorbitol, mannitol, dextrose and sucrose.

39. (New) The solid unit dosage form of claim 6, wherein said filler is a calcium phosphate selected from the group consisting of dibasic, tribasic, hydrous and anhydrous calcium phosphate.

40. (New) The solid unit dosage form of claim 8, wherein said lubricant is a metallic stearate selected from the group consisting of magnesium, calcium and sodium stearate.

41. (New) The solid unit dosage form of claim 15, wherein the active ingredient is in the form of crystals with a median particle size of 40-200 μ m.

42. (New) The solid unit dosage form of claim 15, wherein the active ingredient is in the form of crystals with a median particle size of 45-150 μ m.

43. (New) The solid unit dosage form of claim 15, wherein the active ingredient is in the form of crystals with a median particle size of 50-100 μ m.

44. (New) Crystals according to claim 19, wherein the median particle size of the crystals is in the range of 45-150 μ m.

45. (New) Crystals according to claim 19, wherein the median particle size of the crystals is in the range of 50-120 μ m.

39 46. (New) The method according to claim 21, wherein the median particle size of the crystals in the range of 45-150 μ m.

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cont. 40 47. (New) The method according to claim 21, wherein the median particle size of the crystals in the range of 50-120 μ m.

41 48. (New) The method according to claim 26, wherein the methanol:water weight ratio is in the range of 10:1 to 30:1.

42⁴⁹ (New) The method according to claim ²¹~~26~~, wherein the methanol:water weight ratio is in the range of 15:1 to 25:1.

43⁵⁰ (New) The method according to claim ²²~~27~~, wherein the solvent:solute weight ratio is in the range of 0.7:1 to 2:1.

44⁵¹ (New) The method according to claim ²²~~27~~, wherein the solvent:solute weight ratio is in the range of 0.9:1 to 1.5:1.

45⁵² (New) The method according to claim ²³~~28~~, wherein said first temperature is in the range between 60°C and the refluxing temperature.

46⁵³ (New) The method according to claim ²³~~28~~, wherein said first temperature is in the range between 64°C and the refluxing temperature.

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47⁵⁴ (New) The method according to claim ²⁴~~29~~, wherein said second temperature is in the range of 25-35°C.

55. (New) The method according to claim 30, wherein said holding time is in the range of 1 hour to 4 days.

56. (New) The method according to claim 30, wherein said holding time is in the range of 12 to 36 hours.

50-57. (New) The method according to claim 32, wherein said time span is in the range of 15 minutes to 4 hours.

51-58. (New) The method according to claim 32, wherein said time span is in the range of 30 minutes to 2 hours.

52-59. (New) A method for manufacturing a citalopram dosage form, which comprises

- providing a solution of a pharmaceutically acceptable salt of citalopram in a suitable solvent system at a first temperature;
- cooling said solution to a second temperature below said first temperature;
- seeding said solution with crystals of said citalopram salt;
- holding said solution at said second temperature for a predetermined period of time;
- cooling said solution to a third temperature that is lower than said second temperature to form citalopram crystals having a median particle size of at least 40 μ m;
- isolating said crystals from said solution; and
- directly compressing a predetermined quantity of crystals into a tablet.